

**REMARKS**

**I. Status of the Claims**

Reconsideration of the present application is respectfully requested. Claims 1-4, 7-16, 19-31, 33-37 and 39 remain pending. No new matter has been added by way of this amendment.

**II. Priority**

Applicants note that the request for corrected priority claim was not entered. Applicants thank the Examiner for contacting the Petitions Office for consideration of the previous amendment filed March 20, 2006. Per the Examiner's request, applicants submit herewith a Petition to correct an unintentionally delayed priority benefit claim under 37 CFR 1.78(a)(2). Applicants have provided this petition to the Petitions Office and await for a decision on the merits.

**III. Rejections Under 35 U.S.C. §103(a)**

Claims 1-4,7-16, 19-31, 33-37, and 39 stand rejected under 35 U.S.C. 103(a) as unpatentable over Raad et al. (U.S. Patent No. 5,688,516) in view of Domenico et al. (*Journal of Antimicrobial Chemotherapy*, 28(6):801-810,1991), WO 97/25085, and Darouiche et al. (United States Patent No. 6,719,991). According to the Examiner, Raad discloses a combination of antimicrobials and chelators on medical devices. The Examiner also relies on Domenic for disclosing an antibacterial effect of bismuth salicylate salt; on WO 97/25085 for disclosing the use of anti-infective agents such as chlorhexidine, triclosan, or benzalkonium chloride; and on Darouiche for use of antibiotics and antiseptics on medical devices. According to the Examiner, "the prior art does not expressly disclose" the claimed combinations, but "the prior art amply suggests the same". Therefore, according to the Examiner, it would have been obvious to combine the components in the art to arrive at the claimed invention. Applicants respectfully traverse the rejection and request reconsideration.

As previously argued, Applicants submit that the cited art does not provide all requisites for rendering the present invention obvious. The cited art fails to provide a reasonable expectation of success and fails to teach all elements of the claimed invention. The Examiner's assertions that "the prior art amply suggests" and that "it would have been well within the skill of

one of ordinary skill in the art to modify the prior art" are insufficient basis for a *prima facie* case of obviousness.

Mere awareness in the art is not sufficient to establish obviousness. *See In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001) (Deficiencies of references cannot be saved by appeals to "common sense" and "basic knowledge" without any evidentiary support); *see also Micro Chem., Inc. v. Great Plains Chem. Co., Inc.*, 103 F.3d 1538, 41 USPQ2d 1238 (Fed. Cir. 1997) *cert denied*, 521 U.S. 1122, 1244 (1997) ("A determination of obviousness must involve more than indiscriminately combining prior art; a motivation or suggestion to combine must exist."). Rather, obviousness can only be established where there is some teaching, suggestion or motivation in the prior art that would have led a person of ordinary skill to combine or modify the references. *See In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995); *see also In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants submit that the cited art does not provide the appropriate motivation to combine teachings to arrive at the present invention. Rather, Raad is directed to three factors in controlling catheter colonization by infectious microbes, namely controlling (i) availability of microorganisms, (ii) production of glycocalyx, and (iii) formation of a thrombin sheath at the catheter site. (See col. 1, lines 44-60). Raad is directed to compositions solely for application to inanimate objects, e.g., medical devices. Whereas, the antiseptic component of the present invention (absent altogether in Raad) is used to fight microorganisms of living tissue not for inanimate products. (See published application, ¶2). Domenic provide no additional teaching or insight to Raad in that Domenic discloses that a bismuth salt (e.g., subsalicylate) reduced capsular polysaccharide production. These references provide no motivation to combine an additional component, namely an antiseptic, in the effective amounts claimed.

Dariouche et al. is directed to coating medical devices with an antimicrobial agent and non-pathogenic gram-negative bacteria. (See col. 3:59-4:5). In fact, Dariouche goes into great detail explaining that use of catheters surface coated with only antibiotics or antimicrobials is not effective over time. For example, Dariouche states, "while the surface coated catheter does provide effective protection against bacteria initially, the effectiveness of the coating diminishes over time." (See col. 2:44-47; see also col. 2:40-3:17). Therefore, Dariouche would not lead one skilled in the art to provide a coating material on a medical device without the presence of gram-

negative bacteria. As such, one would not be motivated to combine this teaching with either Raad or Domenic to arrive at the presently claimed invention.

Lastly, WO 97/25085 (hereinafter “the ‘085 publication) discloses the use of chlorhexidine and triclosan and optionally other ingredients including benzalkonium chloride in solution for use in medical devices. (See page 4, lines 13-15 and page 14, lines 3-8). However, the ‘085 publication is specifically directed to the use of these components in polymer based solutions in order to achieve their effective antimicrobial activity. (See page 4, lines 15-21). The polymer component is required to achieve the lasting effects of the antimicrobial components. Furthermore, the ‘085 publication requires the presence of both chlorhexidine and triclosan to achieve the effective antimicrobial effect intended. (See, e.g., claim 1). Thus, one skilled in the art would have had no motivation to use such components without a polymer-based solution. Furthermore, one skilled in the art would not have been motivated to combine Raad (or any other cited art) with the ‘085 publication to attempt to arrive at the claimed invention. Therefore, Applicants submit that none of the references provide any motivation to combine the various components of the art to arrive at the claimed invention.

Without proper motivation provided by the art, the Examiner has used improper hindsight in formulating the present rejection. *See In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *see also In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998) (“To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness.”). The Examiner has merely picked and chosen components from the cited art in hindsight to attempt to arrive at the claimed invention. Accordingly, Applicants submit that none of the references in any combination provide one skilled in the art to arrive at the present invention. Applicants therefore conclude that the claimed invention is not obvious over the cited art, and request that the rejections be withdrawn.

#### **IV. Double Patenting**

Claims 1-4, 7-16, 19-31, 33-37 and 39 stand rejected under the judicially created doctrine of obviousness-type double patenting and under 35 U.S.C. § 103(a) for being allegedly obvious over U.S. Patent Nos. 6,106,505 and 6,582,719 in view of U. S. Patent No. 6,719,991, Domenico et al., and WO 97/25085.

Regarding U.S. Patent No. 6,582,719, applicants hereby agree to submit a Terminal Disclaimer upon notification of allowance of allowable subject matter of the presently pending claims in order to further along allowance of the pending application.

Regarding U.S. Patent No. 6,106,505, Applicants note that U.S. Patent No. 6,106,505 ('505 patent) is directed to the treatment of polymeric medical articles utilizing specific combinations of chlorhexidine and triclosan, both antiseptic agents. The '505 patent does not claim combining an antibiotic and antiseptic agent to treat a polymeric medical article. Even in view of the additional references cited by the Examiner, for the reasons noted above in the nonobviousness arguments, Applicants do not agree that an obviousness-type double patenting rejection applies. Combining the disclosure of the '505 patent with the cited references does not collectively teach an effective combination even to a skilled artisan. One skilled in the art would have no reason to combine the presently claimed components as argued above. Accordingly, the rejection as regards the '505 patent should be withdrawn.

V. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Applicants believe that aside from the fee for the two-month extension of time, no additional fees are due. If however additional fees are due, the Commissioner is hereby authorized to charge payment of fees or to credit any overpayment associated with this communication to Deposit Account No. 02-4377.

Respectfully submitted,

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